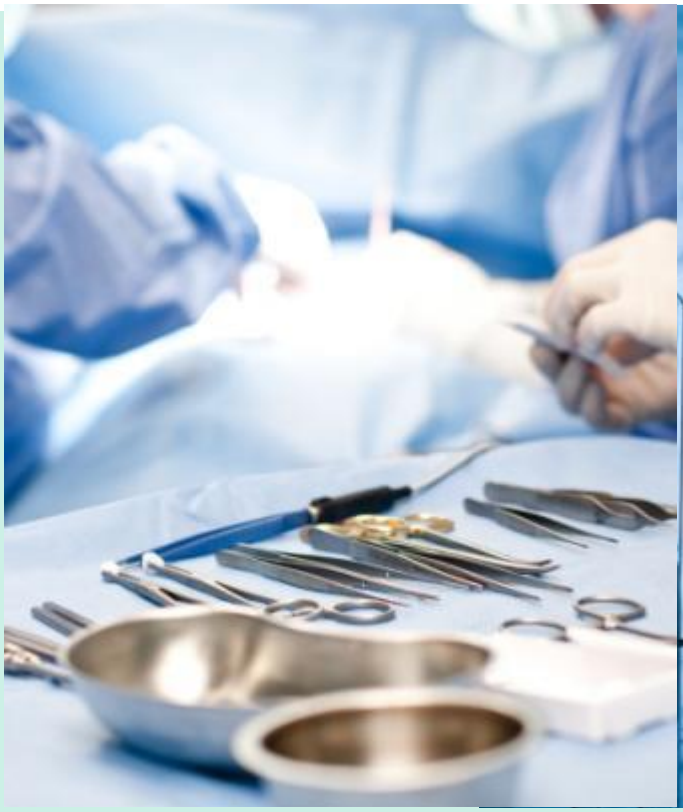
Sterile Goods Logistics Optimization with Containers



Sales Consulting Guide

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Version 1

Prepared by Dr. Gerhard Kirmse, October 2019

Content:

It can be expected, that similar to instruments, the features of a product will become less important compared to the supporting services. An important service with sterile container will be

- to perform the best possible integration of containers into the customers processes
- to tailor solution which in the best way resolve the customers issues.

If in doubt, please contact

- Product related questions: Local and Global Marketing Team (Elmar Heid, Eva Streit, Akiko Maeno)
- Process related questions: Local or Global TCC Team (Dr. Gerhard Kirmse, Lorenzo Castillo-Sohre Kai Tebbe, Angelika Moser)
- Local or Global SAM Team (Thomas Zepf)

1. Main Benefit – Overview. Questions to be answered

As a first step in the process it has to be determined, which are the main benefits a hospital / user wants to achieve (there may be difference between OR, CSSD and other departments)

1. Avoid damaged wrap material: As a rigid barrier system
2. Avoid drying issues
3. Issues in Logistics (handling, space transportation,…)
4. Faster turnaround time
5. Reduction of Cost
6. Workflow
7. ……..

However it has to be observed that the use of containers changes many aspects of a sterile goods logistics and these changes may become a stumbling stone or drawback to use such a system. So it is our job to make sure these are cleared out of the way before implementation.

- The use of containers generally requires more space that the use of soft wraps. So if a CSSDS or sterile stock is under massive constraints, this may be an obstacle.

- Containers change the sterile goods logistics totally and it has to be checked, where they fit into the existing system and where modifications can be made. Some solutions depend on each other:
  a) Do container fit into the **shelving or rail system of the existing sterile stock**? (see **chapter 3.1**)
     - Containers are wider and deeper than wrapped baskets, typically only a few centimeters but this may be enough to hold two containers instead of three baskets in on compartment. Also container system have different sizes.
     - Containers are also typically higher than wrapped baskets. Container can be stacked but most hospitals do this also with wrapped trays, although it is for bidden by the IFU
  b) Do container fit into **carts and trolleys** used for transportation (see above)
     - From sterile stock to OR?

- From OR to CSSD?
- From CSSD to Sterile Stock?

It has to be asked if carts are usually filled completely, so if really more transportation has to be done with containers inside.

c) Do container fit with the **basket system** used? It is a chance to implement Aesculap basket, INOS and/ or silicone mats when implementing containers. (see **chapter 5**)

d) Sterile containers may well serve **as "closed boxes" for transporting dirty instruments** from OR to CSSD. If this makes sense depends on distance and way of transportation. There are many ways, how to do this in detail (covered in **Chapter 3**) and this will drive
   - How large (especially how high) a container for a certain set has to be
   - How thoroughly a container has to be cleaned and disinfected in the CSSD (see **chapter 4**)

e) Sterile containers have to be **cleaned and disinfected**. This is a major change compared to soft wraps however in most countries there are no specific rules, how this has to be done in detail (see **chapter 4**)
   - If there is no contact with dirty instruments (chapter 3) either no disinfection or a manual disinfection is performed.
   - A manual disinfection requires space
   - Machine cleaning requires
     - A special machine cycle
     - Specific loading carts
     - Significant machine capacity

     Cart washer or instrument washer are possible depending on available capacity and container quantity.

f) If washer capacity is a challenge (or sorting) it is an option to use **"neutral containers",** (see **chapter 7**) which works nicely with the AESCULAP Aicon® detachable face plates. This means that washing processes do not have to be synchronized any more but requires
   - Larger holding areas in decontamination and packing (see chapter 3) depending on workflow
   - Extra effort, if a tracking of container use cycles is required (see **chapter 8**)

The concept of neutral container is also explained in the simple show "How to use the new identification system"

g) For the **sterilization process** multiple factors have to be considered (see **chapter 6**)
   - Shall the containers be used with an inner wrap (in some countries partially preferred for aseptic presentation)
   - Shall sterilizers be loaded with containers only or with a mix of containers and soft wraps
     - Mixed loads make drying more difficult
   - Are existing loading carts/system suitable for containers?

- Shall container be sterilized next to each other or be stacked?
  - Stacking increases equipment efficiency but raised drying requirements and slows down the process
- Is the sterilizer cycle suitable for containers as is or does it have to be modified
  - This will definitely be the case if cotton wraps were used before
- To enhance the drying tray liners or the EDS system (see **chapter 6.3**) can be used however successful drying depends on multiple factors
  - EDS does not have a positive effect in combination with inner wrap or tray liners or complex plastic try
  - Using EDS on some hard to dry sets is a good option but does not work well with the concept of "neutral containers"

h) Every hospital wants to send **information** with sets to and from the OR, the label but sometimes much more (see **chapter 8**)
   - The face plates can hold labels up to 102 x 56 mm (T Doc). On wrapped sets larger labels may be used
     - On the face plate set name and department may be placed on tags
   - Additional information may be placed on extra printouts, labels and hangers,
   - Set lists may be included in or on the set
     - Electronic solutions such as TOM are preferable but no always possible
     - If messages from the OR to the CSSD are included these sheets usually are contaminated so special considerations about handling are necessary.

- A **partial containerization** may be an option (see **chapter 9**)
  a) Especially if the major concerns (torn wraps, drying) are related to only part of the sets
  b) If space constraints and washer capacity are an issue
  c) In case of financial constraints

  However partial containerization also lead to a number of challenges: Logistic, loading equipment and labeling has to be fitted for both system. It also leads to the constant need of mixed loads in sterilizers.

2. Approach

The following steps will help to find out the customers need and tailor the best possible solution:

Your tools are: at least one sample container and a tape measure. A contact thermometer and a weighing machine are also helpful. The steps are listed in the checklist (chapter 11).

1. **Understand and analyze the customers situation**
   1.1. Acquire basis statistic data from the Hospital (How many sets available, how many processed per day, how many machine loads))
   1.2. Observe the current process in OR and CSSD, ask and watch for issues
   1.3. Do a test run in the washer (see **chapter 4.7**) and in the sterilizer (see **chapter 6.4**)

2. **Tailor a customer specific solution**
   Options are
   2.1. Full or partial containerization, including small sets, loan sets etc. or not
   2.2. Container tied to set or "neutral container"
   2.3. Use existing baskets/ trays or switch to new
   2.4. Use inner wrap and/ or tray liner
   2.5. Use container for transport of dirty instruments or not (and in which condition of instruments)
   2.6. Use existing transportation carts or switch to new ones
   2.7. Clean and Disinfect container manually of by washer disinfector (may require special racks and validation)
   2.8. Use existing labels or switch to new sizes/ design
   2.9. Can existing loading racks and sterilizer cycles be used? Shall loads be "container only" or also mixed?
   2.10. Do drying and cooling issues have to be expected? Use EDS system or not?

3. **Present your solution, find compromises**
   3.1. Use a results as a base for quotation and tender specification

In case

- the results are inconclusive or
- there are major objections against any possible solutions
- Further analysis of cleaning or sterilization process is necessary

Contact your locally responsible **TCC Consulting**.

A more detailed testing including **full loads** and the targeted processes should be done **between order award and delivery**, earlier if the customer insists

3. Handling in OR, Disposal and Logistics

Containers in general have a large benefit of robust protection against rough transportation conditions. AESCULAP Aicon® is now specifically validated as a sterile barrier system in road transportation (not required by a standard, see D-ST 19067: Test result AESCULAP Aicon® truck transport)

3.1. Storage Shelves /Cabinets, Transportation Carts and Trolleys

Remark: The only standard reference for sizes is EN868 with the "STU (Sterilization Unit)" of 600mm x 300mm x 300mm. AESCULAP Aicon® fits into this system but many shelves trolleys and carts have by tradition been adapted to some type of system.

3.1.1. "Foot Print"

The footprint of the AESCULAP Aicon® Full Size Container is 598mmx 297mm which most likely is slightly larger than what the customer had before and shelf system etc are many time designed for the existing system by the millimeter .

- Aesculap Basic Container 592mm x 284mm
- Wrapped basket (240mmx540mm): ca 550mm x 260mm

So check if AESCULAP Aicon® Container fit into the existing system (rails, shelves, pull out etc) and if the same number of sets can be held in similar space

- Example: 3 Basic Containers side-by-side: 872mm wide,
  3x AESCULAP Aicon® 891mm (if equal height)

3.1.2. Height

AESCULAP Aicon® heights are generally slightly lower than Basic or Primeline but the offered heights do not include 135mm and 180mm any more (150mm instead)

Comparing to wraps an AESCULAP Aicon® 100mm (height) Container will be required to hold a basket with 50mm height (wrapped ca 75mm height). (Remember: For larger Sets two trays can be placed in one container, but not in one wrap)

So check shelf systems also for available height and if a similar number of sets can be held! (Remember: Wrapped sets must never be stacked per wraps IFU, but many hospitals due so due to lack of space))

If new shelves/ carts are needed and future carts shall be evaluated please check our System Compatibility Overview in the toolbox

3.1.3. Shelf Life

Currently we have a study for 180 day shelf life (DocumentD-ST19065) , which will be extended to 360 days (like Basic and Primeline). Depending on current situation (to be checked) and acceptance by hygienic this may allow longer shelf life.

If the hospital purely works based on "event related" shelf life (no date), it can be claimed that events will be reduced with a rigid system (no damage by handling).

3.1.4. Stock Organization

The stock organization may be:

- Fixed place for each set or set type
- Fixed areas for each surgical discipline
- "Wherever is space"

If there are no assigned spaces per set it makes sense to work with color coding and tags to make the set type easier visible from a distance.

3.2. Handling in OR

There are different protocols of opening a sterile set in the OR

3.2.1. Opening the set (soft pack), use wrap as table cover

This system can not be used with a container. A separate table cover has to be used and then the basket is transferred on the cover.

The system of using a soft wrap as table cover does not allow proper inspection of the soft wrap for damages and this therefore not recommend.

3.2.2. Opening the set (container), lift basket out and transfer to sterile table

This is the most efficient method, which allows various ways of disposal (see **chapter 3.3**). There are concerns in some hospitals about lifting heavy sets and also accidentally touching no sterile parts of the container (with AESCULAP Aicon® the edge of the base is now definitely sterile), see Test report D-ST19066 AESCULAP Aicon® base edge sterility

3.2.3. Folding out an inner wrap over the edges of the container, leave basket in container

Using inner wrap requires extra material and effort. We do not recommend this method, but it is possible and some ORs insists due to long term habits. If an inner wrap is used, the EDS system will not have benefits any more.

3.3. Disposal (Transport of dirty instruments)

There are various ways to transport instruments after use fro OR to CSSD. This has influence on the cleaning and disinfection process and also on the required size of the containers.

3.3.1. Container is removed from the OR before case starts

Instruments are transported in baskets / wraps. In this case the Container is regarded clean and no cleaning or disinfection has to be performed (some hospitals still require wipe disinfection depending on the route of transportation)

3.3.2. Only unused instruments are transported in the container

The Container is only slightly contaminated (accidentals spills or touches), most hospitals regard wipe disinfection as sufficient.

3.3.3. Dirty instruments in the container, packed as sterilized

The container requires cleaning and disinfection according to the hospitals standard (see chapter 4). The size of the container is defined by the packed set only.

3.3.4. Dirty instruments in the container, prepared for cleaning

The container requires cleaning and disinfection according to the hospitals standard (see chapter 4). The size of the container then has to be significantly higher

- Instruments may be laid open, the a second basket is recommended
- The instruments may be but on a wide stringer.

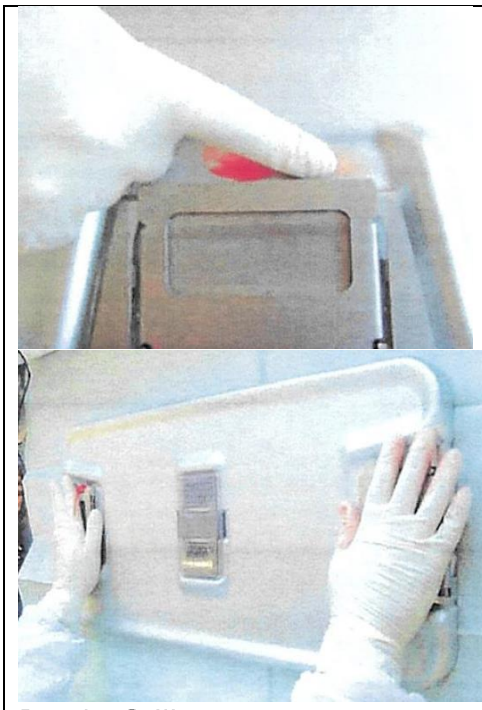
Some hospitals with the methods 3.3.1 and 3.3.2 use extra boxes (plastic or metal) to transport the dirty instruments. These boxes also have to cleaned and disinfected. We do not recommend such solutions as it would be more efficient to use the sterile container (transport and clean only one box instead of two).

4. Cleaning of Containers

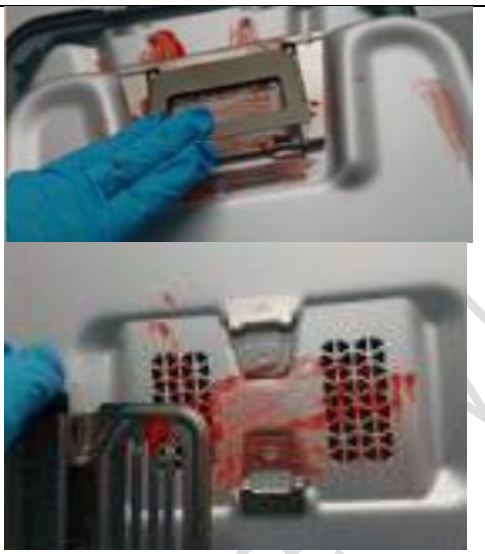
4.1. Performance requirements

As sterile containers have no direct patient contact most countries do not have specific requirements and guidelines about the performance of a cleaning and disinfection process and also hospitals with similar handling may require completely different processes. Negotiation with the hygienics responsible and validation engineers may be possible, if discussion can be done at eye-level (eventually ask specialized consultant / marketing for help). Options are:

- No cleaning and disinfection: Sometimes accepted in scenario **3.3.1,** sometimes not
- Manual cleaning and disinfection (by wiping): Most of the times accepted in cases **3.3.1**. **and 3.3.2** but also in several hospitals for cases **3.3.3 and 3.3.4**
    - Manual disinfectants are grouped by performance against various pathogens (bacteria, virus, funghi, ….). There may be requirements from the hospital regarding this spectrum of efficacy.
    - Remark: a so called “fully virucidal” disinfection is not possible by wiping
    - Aesculap generally recommends the use of alcohol based wipes (B. Braun Meliseptol or similar), which are bactericidal and partial virucidal
- Machine Cleaning: A wide variety of test methods exists to proof successful cleaning, some hospitals do not test at all. Tests may be:
    - Successfully clean an **indicator** such as TOSI or a **Process Challenge Device (PCD)** in the process
    - **Cleaning really used containers** and testing (by swab or elution) for Protein, Hemoglobin or ATP. Exact methods and acceptable limits vary.
    - Same test as above but artificially contaminating the container with blood or a test soil before the process. Testing may be done by visual residue or be Protein Test, ATP test etc.. Sometimes processes have to be extended dramatically because soiling in validation is performed in excessive way (e.g. under filters, inside hand mechanics etc). In such case we should object and lead back to realistic soiling (like really used containers)



Regular Soiling



Excessive Soiling

To have a test method evaluated, please contact a specialized consultant / marketing for help). Aesculap has performed validation testing be handling a container with a blood soiled glove, the cleaning and testing by protein and hemoglobin (see Testresult D-ST 19078 cleaning validation))

- Thermal Disinfection: Performance is calculated by the A°-Method (ISO15883), which is a calculation of temperature and time
    - A°=60: low level disinfection, comparable to surface disinfection (e.g. 80°C, 1min) only accepted in few hospital for containers, mainly used for transportation carts
    - A°=600: mid level disinfection, (e.g. 90°C, 1min), most common for containers
    - A°=3000: high level disinfection, (e.g. 93°C, 1min or 90°C, 5min), mainly used for instruments, in some hospitals also requested for containers

Aesculap Containers can withstand all these temperature if the water quality is suitable (see **chapter 4.7**).

4.2. Manual Cleaning and Disinfection

Reference for correct cleaning and reprocessing always is the current IFU.

If the method is generally acceptable Aesculap recommends Alcohol based wipes (such as BBraun Meliseptol wipes)

- The surface only needs to be wiped, alcohol evaporates and does not leave a residue (no rinsing or drying required)

- Fast, normally sufficient cleaning capabilities
- Easy to handle, available in most hospitals

Remarks: Aluminum is not a "sensitive surface" regarding alcohol, all concentrations and types can be used.

Examples are:

- BBraun Meliseptol
- Borer Deconnex Solarsept
- Dr Weigert Neoform Rapid
- Schuelke Microzid AF liquid
- Ecolab Incidin liquid
- ……

For "**water based" – cleaners and disinfectants** (concentrate mixed with water) the following has to be considered:

- "Surface disinfectants" are made for wipe application but not with items in mind which get steam sterilized. Residue may cause discoloration and surface damages.
- "Instrument disinfectants" are made for application by immersion (longer contact times), which is not suitable for containers
- All water based cleaners and disinfectants have to be rinsed off and the container afterwards dried (see IFU), which is a time and space consuming process

4.3. Washer Cycles general

Major goals for a washer cycle are:

- "aggressive" enough to ensure proper cleaning
- Not too "aggressive" to avoid chalking and surface changes
- Fast cycles to make best use of machine capacity

General Recommendations are

	Step	Parameters	Comments
1	Pre Clean	Soft Water Cold, 1-3min	In our opinion not required, unless containers are really heavily soiled, sometimes requested by detergent manufacturer
2	Clean	See below	Most critical process step
3	Intermediate Rinse	1-2min Soft or demineralized water	Avoids transfer of detergent into thermal disinfection, if warm water can be used it saves time, If this step is not used, material compatibility has to be carefully tested
4	Thermal Disinfection	A° see **4.1** demineralized water	Rinse aid may be used (except for Primeline plastic) if aluminum compatible, no lubricant should be used (staining), if soft water is used, material compatibility has to be carefully tested

5	Drying	Depends on machine, Maximum Temperature	It is difficult to get container "dust" dry. We recommend to accept some residual moisture (e.g. 0,5ml per part) to achieve shorter cycles)

Cleaning parameter depend on performance requirements (see 4.1). Our IFU asks for 10min at 55°C (aggressive side), 5min at 45°C will also be sufficient in most cases (less aggressive).

Aluminum reacts sensitive against high pH, therefore neutral cleaners shall be preferred, "mild alkaline" cleaners may work but need careful testing, "high alkaline" cleaners are not suitable.

Neutral (Enzymatic)	Mild alkaline	(high) alkaline
B. Braun cleaner neutral	B Braun Cleaner MA	B. Braun Cleaner Alkaline
B Braun Cleaner Enzymatic	Dr Weigert Mediclean	Dr Weigert FA
Dr Weigert Medizyme	Dr Weigert Mediclean forte	Dr Weigert Duoclean
Ecolab FRE	Dr Weigert System Alpha	Dr Weigert Septoclean
Schuelke ER	Ecolab Multiclean	Ecolab ProClean
Schuelke RKN zym	Ecolab MetalClean (Solid)	Ecolab PR (Solid)
Steris 2x enzymatic	Schuelke Thermosept Xtra	Schuelke Alka Clean forte
Steris 2x neutral	Steris 2x alkaline	Borer alka one
Getinge enzymatic	Borer twin basic / zyme	
Belimed enzymatic	Getinge universal	
	Getinge MIS	
	Belimed Mild alkaline / Mild alkaline enzymatic	

In some countries also cycles with **thermo-chemical disinfection** may be used. These chemicals are not listed here as these cycles are significantly more difficult to evaluate. Please contact TCC with a process description according to the table above, if such processes are discussed at your customers.

A claim, that a cleaner is „aluminum compatible" is not a guarantee against damages. Water quality in cleaning is ambiguous. Demineralized water may raise the pH (reduced buffer capacity) but also high carbonate content in soft water may have such an effect.

Typical damages are "Chalking" and discoloration of color anodized parts.

Pictures Chalking

Recommendations against chalking are:

- Use neutral detergents, wherever possible. Dosage should be on the low end of the manufacturer recommendation (especially mild alkaline)
- Temperature of cleaning should be low (45°C). increase temperature raises aggressivity of the cleaner
- Cleaning should not longer than necessary
- An intermediate rinse should be used to avoid carry over of cleaning into final rinse

We have also seen case where highly purified water (conductivity below 1µS) in final rinse has caused an issue. We recommend to always test a cleaning process for material compatibility according to 4.7.

4.4. Instrument washers

In instrument washer always a special loading rack is required for containers, which typically hold 4-6 containers per load (depending on washer and container size).

- If such a rack is not yet available at the hospital: Check our System Compatibility Chart in the toolbox. for suitable options.
- If a rack is already in use
  - Check by test containers if the AESCULAP Aicon® Container and lid fit in into these racks
  - Check if an acceptable drying results is achieved

  If the existing rack is not suitable, check our System Compatibility Chart for alternatives.

Container should not be washed in instrument programs as they are usually too aggressive and take too much time. Typical Container Programs in instrument washers last 25-45min, depending on cleaning and drying requirements. If additional chemistry shall be installed, it has to be checked if pumps are available and where canisters can be placed.

Example (the time in “Parameters” is t the active time, the time in “step” includes filling, draining and heating):

	Step	Parameters	Comments
1	Pre Clean 3min	Soft Water Cold, 1min	Not absolutely needed
2	Clean 8min	5min at 45°C	Neodisher Mediclean forte 2ml/l In soft water (mix of warm and cold)
3	Intermediate Rinse 3min	1min demineralized water	demineralized water
4	Thermal Disinfection 8min	A° 600 90°C 1min	Neodisher Mediklar 1ml/l demineralized water
5	Drying 10min	120°C ingoing air	Some water residue accepted
Total cycle time : 32min (Instrument program typically 45min -60min)			

4.5. Cart washers

Cart washers are more suitable for large volume goods such as containers. The necessary loading cart first depends on the spry mechanism (sides only or spray arms).

There are various constructions and you have to check if container of all sizes (1/2, full etc) and depths can be safely held in the racks. Depending on positioning and shape of the container complete drying may not be possible.

Capacity depends on container sizes and similar scenarios as **chapter 3.1** may occur, as AESCULAP Aicon® containers are slightly bigger than BASIC. If the existing rack is not suitable, check our System Compatibility Chart for alternatives.

Depending on their construction cart washers take more time for filling and heating. Some recycle part of water for subsequent steps or cycles, which may have an impact on material compatibility. Todays cart washers use mainly thermal disinfection.

Drying performance usually is worse compared to instruments washers. General rules are

- Position is crucial
- Items on higher levels dry better than on lower levels
- Rinse aids improve drying performance

Example (the time in “Parameters” is t the active time, the time in “step” includes filling, draining and heating):

	Step	Parameters	Comments
1	Pre Clean 5min	Soft Water Cold, 1min	Not absolutely needed
2	Clean 9min	5min at 45°C	Neodisher Mediclean forte 2ml/l In soft water (mix of warm and cold)
3	Intermediate Rinse 3min	1min demineralized water	demineralized water (some machine use reduced rinsing)
4	Thermal Disinfection 15min	A° 600 90°C 1min	Neodisher Mediklar 1ml/l demineralized water
5	Drying 15min	100°C ingoing air	Some water residue accepted
Total cycle time : 47min			

If you should run across cart washer, which use chemical disinfection, contact your local TCC consultant, if any questions occur.

4.6. Capacity calculation

If machine cleaning is desired, the required capacity increases significantly when switching from soft wraps to containers. Here you find a calculation scheme with an example for an instrument washer and for a cart washer:

No	Description	Calculation	Instr. Washer Example	CWA Example
1	Work time of CSSD e.g 10.00-22.00	12h		
2	Number of available machines		5	1
3	Total usable time (minus 20% Safety)	1 x 2 x 0,8	48h	9,6h
4	Sets used per day		120	120
5	Cycles used per day (all) (from cycle counters/ maintenance)		39	4
6	Cycle time for current cycle		60min	45min
7	**Remaining usable time**	**3 – (6 x 5)**	**18h**	**6,6h**
8	Containers per load		4	24
9	Cycle time for container (plan)		30min	50min
10	**Time required for container (full containerization)**	**(4 / 8) x 9**	**15h**	**4,1h**
11	Container Capacity	10/11	1,2	1,6

In case:

- If the ration 11 is below 1,0 the desired number of containers can not be processed and partial containerization (**chapter 9**)or manual cleaning has to be considered
- Between 1,0 and 1,5 a **non-synchronized** process may be done and a concept of neutral container can be considered (see **Chapter 7**)
- Above 1,5 a **synchronized processing** of instruments and containers may be considered

If no satisfying solution can be found or usable times are difficult to estimate, a more sophisticated calculation may be done by a TCC consultant,

4.7. On site Testing / Aluminum Compatibility

If the designated container process is not established yet, you may ask your local TCC consultant for an estimate for material compatibility. The process should be described in a table like **chapter 4.4/ 4.5**. For proper cleaning performance the requirements have to be defined **(see chapter 4.1)**

Pre test:

Aluminum test plates (silver (evtl. also colored) is washed in the designated process for 10 times consecutively with maximum 2 cycles per day.

If no surface change occur (wipe test by finger) the process can be regarded material safe.

This test is more aggressive as regular use, so if this test fails, a "real life test" shall be performed.

Real life test:

Aluminum test plates (silver (eventually also colored, ideally also a container) treated in following process:

- Cleaned in the designated process
- Cool down (minimum 1h)
- Sterilized (no packaging)
- Cool down (minimum 2h)

This cycle shall also be performed for 10 times. If no surface change occur (wipe test by finger) the process can be regarded material safe.

If in doubt (e.g. Multiple processes may be used), contact your local TCC consultant. Test plates can be ordered from TCC.

5. Packing and Inspection

Aesculap recommend visual **inspection** of containers for damages (see instruction for use and Video Clip AESCULAP Aicon® Functional Check). Other tests (like water test, smoke test etc) are not recommended as they take extra time and effort and may produce false positive or false negative results.

Oiling if locks has be performed when action becomes stiff or sticky

It has to be checked if existing **baskets** fit into containers. Some baskets designed for wraps are slightly wider than containers.

Discussing a container system will always be a opportunity to discuss baskets:

- Better instrument protection and handling by mesh baskets compared to wire baskets
- Additional protection by AIOS System

The new AESCULAP AESCULAP **Aicon® baskets** can be equipped with tags and offer adapted heights and improved instrument protection.

The use of **"tray liners"** (absorbent sheet underneath the tray) may be a simple method to improve the drying performance. If the sterile barrier system is changed it should always be checked if try liners are still needed. Tray liner to not work together with the EDS system, as moisture is absorbed and will not reach the valves any more (**see chapter 6.3).**

Some hospitals use **inner wrap material** either for aseptic presentation in the OR (**see chapter 3.2**) or they believe that a 2nd "sterile barrier" will make the system safer. The is not indicated by any standard or test results but some people still hold on to this idea from ancient days. Inner wraps mean significant extra costs and packing time so it should be carefully discussed, if they are really needed.

Inner wrap from paper or linen may improve drying, inner wraps from polypropylene or mix material have negative effects. The EDS System does not work with inner wraps (see above).

6. Steam Sterilization

Remark: AESCULAP Aicon® up to date is not released for other sterilization methods than steam.

6.1. Sterilizer Loading

Similar to shelving and storage (see **chapter 3.1)** it has to be checked if AESCULAP Aicon® fits to existing sterilizer loading carts or mechanism:

- "Footprint": Can a similar number of sets be sterilized in one load?
- Height: Depending on stacking: Do desired containers fit into existing carts and can a similar quantity be sterilized in one load?
- If a direct loading system is used
    - AESCULAP Aicon® may be stacked with maximum 3 containers by standard tests
    - Check if AESCULAP Aicon® works with the loading/unloading mechanism

Example loading cart

Example direct load

General rules for loading a sterilizer are:

- Heavy sets to the bottom, light items to the top
- Containers on top of containers, soft packs on top of soft packs
- Maximum chamber load not to exceeded
- Only compatible containers can be stacked (AESCULAP Aicon® is not compatible with Basic / Primeline)

These rules can be challenging to observe, if partial containerization or a mix of system is used. Neglecting is common reason for wet sets.

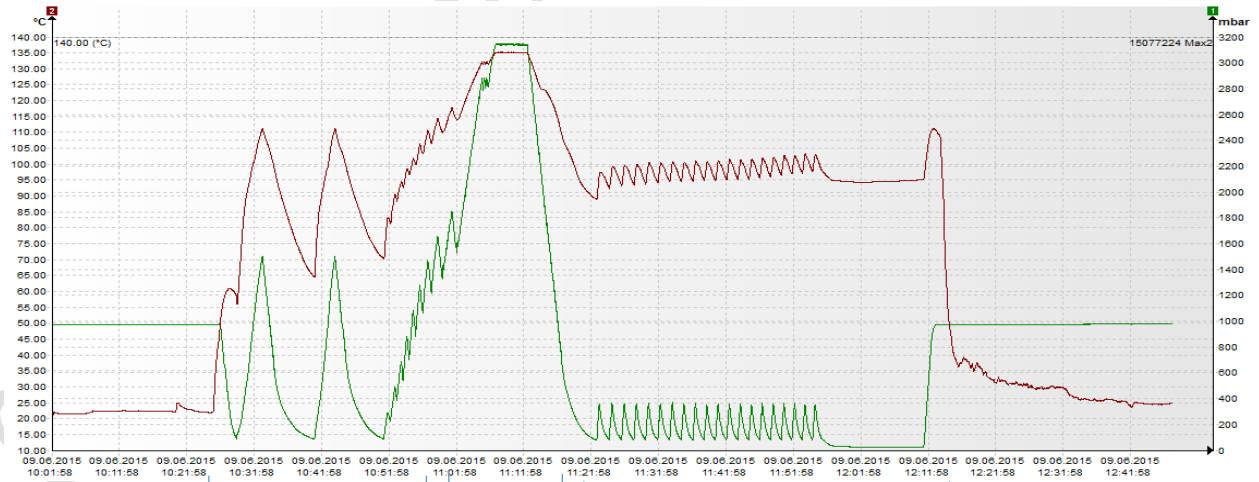
6.2. Cycles

A sterilizer cycle generally consists of three phases

1. **Air removal and heating phase:** This is designed by the sterilizer manufacturer and depends on the type of goods. It is type tested by the manufacturer and can normally not be changed on site. It shall ensure complete removal of air and homogenous heating of goods to the sterilization temperature with the lowest amount of condensate remaining on the products. There are significant differences between cycles for metal loads (instruments etc) and porous goods.
2. **Sterilization phase:** Standard parameters depend on countries and range from 132°C 4min (USA) to 134° 18min (France, Switzerland). Other temperatures (121°C and 143°C) should not be used for instruments. These cycle parameters do not trigger a different behavior of sterile barrier systems. The correct sterilization phase is in many countries verified by indicators.
3. **Drying**: The drying process can be set according to user requirements **(see chapter 6.3)**

- The pressure achieved depends on the equipment and installation of the sterilizer (may range from 20mbar to 80mbar)
- Time (ranges from 15-45min)
- Fractioning (or pulsing): pressure variation can improve the atmosphere and heat transfer in the chamber

The indicated chamber temperature (by the sterilizer) does not give a real information about the drying performance as the sensor usually is placed in the drain and doe not reflect the temperature of sterile goods.



Green: pressure curve red: chamber temperature

The drying behavior depends on multiple factors:

- **Sterilized Goods**
  - **Type of Goods:** 10kg of metal goods produce about 300ml of condensate during heating, plastic goods up to three times as much. Plastic good are much harder to dry than metal goods (silicone mats, plastic trays etc also have negative influence)
  - **Weight of goods:** Heavier packs produce more condensate and are therefore harder to dry. Aesculap recommends a maximum content of 10kg inside a container.
  - **Sterile Barrier System:** Usually container are easier to dry than soft packs, but this strongly depends on the material of the soft pack:
    - **Cotton wraps:** need very short dry times, modification will be needed when switching to Containers
    - **Paper wraps:** Rather good drying behavior but low stability
    - **Polypropylene Wraps (SMS) or mix:** Usually difficult drying, depending on thickness
  - **Tray liner:** Absorbent sheet underneath the tray are a common and easy method to improve the drying in containers and soft wraps

- **Load:**
  - **Total weight of Load:** More weight in the chamber produces more condensate and makes drying difficult. Manufacturers of sterilizer sometimes use quite light reference loads such as 10kg per STU (0x30x30cm). If this load is exceeded drying has to be adapted.
  - **Load/Position:** Soft packs drip condensate in the drying phase, containers in the heating phase, depending on weight. Therefor heavy goods shall always be placed at the bottom, light goods at the top. Goods at the bottom take the dripping from goods above and are therefor harder to dry- In some sterilizers goods at the door dry worse than in the middle.
  - **Mixed Loads:** Mixed load make drying difficult, therefore
    - Porous goods shall run in separate loads from instruments (also to avoid staining issues)
    - If soft packs and containers are in one load
      - Soft packs shall be placed above soft packs
      - Containers shall be place above containers
      - Very light packs are not an issue as they hardly produce condensate

- **Sterilizer**
  - **Size:** Large sterilizers generally take longer dry times than small ones
  - **Steam Quality:** Wet steam can be a reason for random wet loads and packs. Especially if steam production is not integrated into the sterilizer condensate removal from pipes is crucial
  - **Vacuum:** Depending on construction and cooling the minimum pressure in vacuum may reach from 20mbar to 100mbar. Lower pressure improves drying significantly

- **Cycle**
  - **Dry time:** Longer dry time will usually improve drying but only up to a certain limit. Dry time of more than 45min are usually not effective as the chamber gets saturated with moisture.
  - **Pulsing:** Pulsing helps by drying the chamber atmosphere and transferring additional heat. Not all sterilizers are capable of pulsed drying.

- **Handling**
  - **Before:** Goods loaded into the sterilizer should be dry and at room temperature. Colder and moist goods will produce more condensate and will be more difficult to dry.
  - **After:** Goods shall cool down on the loading rack for at least 30min. Handling may create cold spots where condensate collects

Usually goods sterilized in a CSSD will have a wide range from easy to dry to hard to dry. The drying performance has to be adapted to the latter ones, as wet sets mean a major issue in the OR.

The actually used drying time is driven by the "hard-to-dry-sets" while a majority could be sterilized with a shorter drying cycle. This may lead to the use of two different cycles (typically called "normal" and "heavy goods",) but this may lead to user errors, when a wrong cycle is selected.

Frequently only dry time is considered as a solution to "wet-set-problems" but you should also consider

- Split of sets (reduction of weight)
- Loading
- Sterile Barrier / Tray liners
- Technical issues (Vacuum, Steam quality)

6.3. AESCULAP Aicon® EDS System

The AESCULAP Aicon® EDS is another option, so resolve such challenges. For the function of the system please see the Simpleshow What means EDS The EDS system requires that condensate makes its way to one of the valves to bring a benefit, which means

- The container must be leveled (horizontal) during the sterilization
- No tray liner used
- No inner wrap used
- Also multilevel plastic trays or bowls may prevent the condensate from moving to the valves

The EDS system can be implemented in two different ways:

- Only "hard-to dry-sets" are packed in EDS containers, others in normal containers. This will cut back the dry time of these sets (e.g. 30min) and equalize it to the "easy-to-dry"-sets (e.g. 20min).
- All containers are equipped with EDS. This will not further shorten the dry time (compared to the first option) but it males the handling easier (especially under a system of "neutral

container", **see chapter 7**) as no differentiation between the two types (with and without EDS) is required but costs are increased.

6.4. On-site Testing Sterilization

We recommend the following procedure to do an on site testing, if the current sterilization process isn roughly suitable for containers:

1. Load a full size sample container with a heavy and difficult to dry tray(s)
    - According to the most likely packing scenario at this customer (inner wrap …)
2. Put it on the bottom tray of a full chamber load, at the door
    - If mix loads (see chapter 6.1 and 9) are a target, place a heavy wrapped set above a container
    - If mixed load are unlikely place another container or a light soft wrap on top
3. Sterilize the load
4. Open the container 30min after the cycle is finished and visually check if the interior is dry

Picture load

Mositure found

The following shall be recorded:

- Picture of the total load and the set in the container
- Estimated weight of test set and total load
- Sterilizer cycle, especially dry time, pulsing and vacuum
    - Usually you will be able to get a printout of the cycle with most of the data but usually the vacuum level has to be recorded manually
- Result: Pictures of moisture found, if applicable

In case

- moisture is found: see **chapter 10** Further Consulting

- chamber s are heavily stained: the stains may be found also on the container in the long term, therefore: see **chapter 10** Further Consulting
- no issues detected: see **chapter 2** for the overall approach

7. Concept of Neutral Container

Traditionally a container is linked directly ("married") to a specific set. This has several advantages

- Container is tagged with the set name
- Container may be color coded
- Usage is traceable together with the set
- Size of container can be tailored to the specific sets

On the other hand this system has significant disadvantages

- Processes of cleaning and disinfection of containers and instruments have to be synchronized so the container is available when the set is packed. This is especially challenging when washing capacity is limited
- Especially in larger CSSDs it takes significant search time to bring container and set together

The AESCULAP Aicon® container lends itself to a concept of a **"neutral container",** which means that a set can be sterilized in any container of the right size. The set can be marked on the outside

- Only with the production label (typically if each set has a specific storage location in the sterile stock)
- With face plate (option of color coding) and production label
- Face plate with tags (additional coding, larger writing of set name)

In the process this process works this way:

- In Decontamination face plate and container are separated, the face plate is washed and disinfected with the instruments.
- Dirty Containers can be kept in decontamination until washing capacity is available
- When the instrument set is packed, any container of the right size (typically the size is noted in the set list) can be taken.
    - Typically an inventory of clean containers on is kept on the packing side
    - Face plate and label are attached to the current container
- The set is sterilized

The following considerations have to be made:

- The additional required number of containers has to be calculated:
    - Typically we recommend a number equivalent to the quantity of sets being processed in 2-4h during peek time (typically afternoon in the CSSD).

    - This is the typical very busy time period when it would be hard to hold back sets to wash containers. Once the number of sets slows down, container washing can be started.
- The storage space for these containers has to be calculated (in decontamination and in packing). This is many times seen as a major obstacle, however
    - 25-50 containers 8depending on size) can be store in a 1m-wide shelf of 180cm height
    - Hospital using containers typically already have storage space for containers waiting for sets and vice versa, which can be used
    - Hospitals using soft wraps have space for the wraps and sometimes extra large tables
- Container Sizes should be harmonized as far as possible. Multiple sizes make it difficult to keep sufficient stock
- I has to be decided, if washing and disinfection of container bases and lids shall be tracked. This would give a full proof of decontamination and life cycle but require extra scanning.

8. Labeling and Tracking

All hospitals have a current standard for information they want to provide with the Set from CSSD to OR and on the way back. This may be

- Set Name, Lot Information , Production Date, Expiry Date, Packer (typically on the production label)
- Department
- Missing Instruments (preferred on the outside of the set)
- Set content list (outside or inside)
- Designated for which procedure
- Additional label for patient file
- “Loaner System”, Priority,….

On the way back from the OR, additionally

- Detected defects, complaints
- Priority of reprocessing
- “Loaner System” etc
- Special risks

AESCULAP Aicon® offers a wide range of options but all systems can be transferred one to one

- On the container or face labels up to 102 x 56 mm can placed (center)
- In the clamps any size of list or labels can be held on the outside
- Up to three small or two large tags can be fixed on a dace plate
- An additional label holder 80x35mm can be attached
- Hangers (printed or for additional labels) can be attached to the face plate

However it has to be checked if an existing solution has to be modified. This may be a stumbling stone but also an opportunity

- Which information is really used?
- Reading from a distance (color code) or studied closely (print)?
- Who needs access to this information and when (inside or outside)?
- Which hygienic considerations are made?
- Is an electronic information more suitable (set lists, transfer from Decontamination to Packing)
- Risk of loss of information outside?

Based on this information a new concept may be designed.

If all **process steps** of container shall be **tracked,** is answered in various ways and (similar to cleaning) most countries do not have specific guidance (decision by hospital):

- Containers have no patient contact
- A proof of successful disinfection may be desired, but most hospital do not perform this for all (single instruments, bowls, …). Many time an organizational solution is regarded sufficient.
- A link to surgical cases is rarely required. If this requested, lid and base must be tracked
- A counting of life cycles may be requested (e. g. for permanent filters, gasket). In this case lid and / or base must be tracked

9. Full and Partial Containerization

There may be several reasons, why a full switch from soft packs to containers is difficult to establish

- Lack of capital money
- Insufficient washer capacity
- Resistance from specific departments
- ….

In these cases a partial containerization may be an option, to make advantage of the benefits of containers in the most critical areas. Examples are:

- Containerization of specific departments only
- Containerization of heavy sets (to reduce damaged soft wraps or wet sets)
- Containerization of frequently used sets (to reduce consumable costs)
- ….

However a partial containerization will create several additional challenges, so it has to carefully planned and tested:

- Storage and transportation systems have to be suitable for both systems
- Personnel in OR and CSSD has to be trained on both systems
- A label and information system (see **chapter 8**) has to be created which suits both systems
- Space for both systems is needed in packing
- Most likely mixed sterilization loads will be executed which are difficult to dry
- Stacking of soft wraps and containers is not suitable

Several of these issues also occur if different container systems shall be used at the same time in process

- Stacking of different container systems is not possible

If a full containerization is desired, extra containers have to be made available for loaner system (not all of these trays fit into containers at all). Also a solution for small sets (for example 10 instruments) has to be found.

If financial constraints are the drawback you may consider **fleet management** or other payment options.

10. Further Consulting

It is our goal to offer the customer enhanced support to integrate Aesculap containers flawlessly into their process. This may happen in two scenarios in the sales process

- The customer has an interest in containers but does not want to purchase unless questions and concerns are settled
- The customer already has placed the order and we want to ensure a flawless implementation

Consultants from TCC and SAM may help you with the following scenarios

- There are concerns about **hygienic questions** in OR, transportation, cleaning, disinfection or sterilization
- No satisfactory solution can be found for **cleaning and disinfection**
    - A detailed calculation fro **capacity** of washers etc. is required.
    - Aluminum shows **surface changes** after cleaning and disinfection
- There are doubts **drying in sterilization**
- A detailed **cost comparison** of container and soft wraps is required
- The customer s requires a more detailed project planning and extended support

Please contact your local SAM or TCC responsible for details

11. Customer Checklist

Tools: Sample Container, tape measure, camera

Area	No	To be checked	Reference
General	I.	Overall Approach What to do in which stage of the project?	2
	II.	Full or partial containerization more feasible? Which wrapping material is used	9
	III.	Further Consulting necessary?	11
Sterile Stock / Transportation	I.	Do shelf systems etc. fit AESCULAP Aicon® containers? Will storage capacity (by number of sets) increase o decrease?	3.1
	II.	What is the current shelf life? Will there be an improvement by containers?	3.1.3
	III.	Does each set or set type have a specific location?	3.1.4
	IV.	Can AESCULAP Aicon® Containers fit into existing transportation carts? Will storage capacity (by number of sets) increase o decrease?	3.1
	V.	What types of labels are used on the outside of packs? Will they fit containers?	8
OR	I.	If wraps used: Are they properly inspected? Used as table drapes? Are damages reported?	3.2
	II.	Are inner wraps used in containers / Are there specific requirements for aseptic presentation?	3.2
	III.	How are labels and set lists used?	8
	IV.	Hoe does disposal of dirty instruments work? Separation of used and non-used instruments? Is a closed box required fort the way of transportation? Are instruments opened/ organized on stringers….? Are there other options?	3.3
	V.	Are issues known with wet sets? How often? Specific sets?	6.2
CSSD Decontamination	I.	Is there space for storage of dirty containers (Option of neutral containers)?	7
	II.	Is washer capacity available for containers? If not may manual cleaning be an option? "Neutral container" may be an option if wash capacity is tight	4.6 4.2 7
	III.	Is there already a cycle and / or carts suitable for containers? Does AESCULAP Aicon® fit these carts? Would other carts be available by the manufacturer?	4.3-4.5
	IV.	Is a testing or validation of the cleaning process required? What will criteria of success be?	4.1
	V.	Which detergents are available? Which may be suitable?	4.3

	VI.	If cycle available: perform test with container Check, if aluminum gets damaged	4.7
CSSD Packing	I.	Is there currently a storage area for sets/ containers waiting for packing? Could extra containers be stocked there (neutral container)?	5 7
	II.	Will there be space saving by switching to containers (extra wrapping tables…)?	5 7
	III.	Are inner wraps/ tray liners used in sets? Are there specific reasons?	6.2
	IV.	Do existing baskets fit into containers? Is there a sufficient protection of delicate instruments?	5
	V.	Which kind of labels and papers are used in and outside? Specific Background? Will existing labels, hangers etc fit to the container? Alternative solutions?	8
Sterilization	I.	Do containers fit on the current sterilizer loading cart?	6.1
	II.	Will the capacity of a sterilizer load increase or decrease when using containers? How would a load look like? Stacked container or single layer	6.1
	III.	Would there be mixed loads of containers and wrapped sets? Which type/ weight?	6.2
	IV.	Does the sterilizer cycle show unusual settings?	6.2
	V.	Are issues known with wet sets? How often? Specific sets? Is there an idea about reasons? Can the EDS system be used in a beneficial way?	6.2 6.3
	VI.	Execute test sterilization with Test container	6.4
Dispatch	I.	Is a cool down period kept? Would it work for containers?	6.2
	II.	How is transportation done? Would it work for containers?	3.3

Further Activities:

see Chapter 2 (Approach) and 11 (Further Consulting)